TARGET ORGAN DAMAGE IN AUTOIMMUNE DISEASES

Release Date: February 26, 1999

RFA: AR-99-003

P.T.

National Institute of Arthritis and Musculoskeletal, and Skin Diseases
National Institute of Dental and Craniofacial Research
National Institute of Allergy and Infectious Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Child Health and Human Development
National Institute of Environmental Health Sciences
National Institute on Deafness and other Communication Disorders
National Eye Institute
National Heart, Lung and Blood Institute
National Institute of Neurological Disorders and Stroke
National Institute of Mental Health
Office of Research on Women's Health

Letter of Intent Receipt Date: April 9, 1999
Application Receipt Date: May 12, 1999

THIS RFA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS RFA.

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases NIAMS), the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Environmental Health Sciences (NIEHS), the National Institute on Deafness and other Communication Disorders (NIDCD), the National Eye Institute (NEI), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Mental Health (NIMH), and the Office of

Research on Women's Health invite applications for research on the genetic bases and molecular pathways of target organ damage in rheumatic and autoimmune diseases. The applications may be for individual research projects (R01), for a group of independent research projects that use the interactive research project grant (IRPG) mechanism, or for exploratory/developmental grants (R21). The research should be specifically targeted towards identification and evaluation of cellular and molecular pathways involved in organ damage and on the genetic basis for target organ involvement in autoimmunity. This Request for Applications (RFA) solicits basic, translational and clinical research projects, but not epidemiological or clinical reatment projects.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Target Organ Damage in Autoimmune Diseases, is related to the priority areas of chronic disabling conditions and of older adults and preventive services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01), interactive research project grants (IRPG), and the exploratory/developmental grant (R21) mechanisms. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The anticipated award date is September 30, 1999. Because the nature and scope of the research proposed in response to this RFA may vary, it s anticipated that the size of an award will also vary. This RFA is a one time solicitation. Future unsolicited competing continuation applications will compete with all investigator initiated applications and be reviewed according to customary peer review procedures.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC Program Director or Principal Investigator should be included within the application.

R01 Applications. R01 awards will vary in size and duration reflecting the nature and scope of the research proposed. Future unsolicited competing continuation applications will compete with all investigator initiated applications and be reviewed according to customary peer review.

IRPGs. The IRPG mechanism encourages interaction and collaboration among independent scientists with common goals. It is intended to bring together research projects from investigators who wish to collaborate but who do not require extensive shared resources. There should be constructive interchange of ideas, data and/or materials. A minimum of two independent investigators are encouraged to submit concurrent, collaborative, cross-referenced individual regular research (R01) applications. These applications must be free-standing and contain independent hypotheses and aims. An application that provides only a service to other applicants is not acceptable. Applicants may be from one or several institutions. Potential applicants contemplating the submission of an IRPG should contact the program official listed under INQUIRIES as early as possible. Guidelines for preparing IRPG applications are available from the program official or from the internet at: http://grants.nih.gov/grants/funding/irpg.htm.

R21 Applications. Investigators with expertise on the physiology, pathology and genetics of organs and tissues involved in rheumatic, skin and autoimmune-related cardiovascular diseases who wish to establish research programs in the context of autoimmune diseases are encouraged to apply. Also encouraged are investigators with expertise in immune mechanisms of disease and autoimmunity who wish to expand their research to mechanisms of target-organ damage.

Exploratory/developmental studies are not intended for large scale undertakings nor to support or supplement ongoing research. Instead, investigators are encouraged to explore the feasibility of an innovative research question or approach which may not be justifiable through existing research to compete as a standard research project grant (e.g., R01), and to develop a research basis for a subsequent application through other mechanisms, i.e., R01, P01.

Exploratory/developmental (R21) grants, may not exceed $75,000 per year in direct costs, not including indirect costs for collaborating institutions, if any. The total project period for an R21 application submitted in response to this RFA may not exceed three years. These grants are

non-renewable and continuation of projects developed under the R21 program will be through the traditional unsolicited (R01 or P01) grant programs.

FUNDS AVAILABLE

It is anticipated that 10 to 15 awards will be made as a result of this RFA.
The estimated funds available for the first year of support for the program are $3.0 M. Actual funding is contingent upon receipt of a sufficient number of scientifically meritorious applications. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and the availability of funds.

RESEARCH OBJECTIVES

Background

Although immune dysregulation plays a major role in the induction of autoimmunity, recent evidence suggests that structural and functional properties of target/end organs such as heart and blood vessels, kidneys, synovium, skin, thryroid gland and islet cells may contribute significantly to the development of tissue damage and clinical disease. Some of the deleterious effects of autoreactivity are likely due to interactions between antibodies and specific cellular elements in the target organ beyond the activation of the complement cascade. For example, autoantibodies may bind to cell surface receptors, and trigger cell activation, modify cell function or induce apoptosis. Relatedly, some of the deleterious effects of autoreactivity may also be due to interactions between cells, such as, sensitized T cells, and associated cytokines, within the target organ. For example, sensitized T cells may trigger cell death and induce the release of proinflammatory cytokines which then may activate cells and alter cell functions. Further, the type of interaction may influence clinical expression and may relate to the observed differences in organ involvement among patients with the same diseases. In lupus nephritis, pathogenic immunoglobulins produce distinguishable deposit patterns in specific glomerular locations and this is associated with different disease profiles. The differences appear to be based on the differential reactivity of the autoantibodies with specific glomerular antigens, suggesting that antigen display in the target organ influences tissue damage.

The genetic mapping of susceptibility genes in diabetes and lupus also suggest an important role of the target organ in the induction of tissue injury, with contributions made by the cellular components and their interactions with the extracellular matrix, independent of other known factors such as HLA. For example, in murine models of systemic lupus, nephritis is differentially

induced in different strains of mice, in spite of similar autoantibody profiles and in the presence of similar T cell reactivity. Recent data from genetic analysis of backcrosses of autoimmune prone mice in a model of autoimmune myocarditis also suggests that genetic factors unrelated of immune-related susceptibility loci are important in the development and severity of symptoms.

In studies of rheumatoid arthritis synovium, specific mutations in the p53 genes have been found and cultured synoviocytes from rheumatoid arthritis patients over-express certain pro-inflammatory genes that are potentially relevant to lymphocyte and monocyte entry and interactions. The features of the genes identified in these mesenchymal cells suggest that they facilitate localization of immune reactions to the joint through leukocyte chemokinesis, cell-cell adhesion, and matrix specialization. These results suggest that intrinsic lineage characteristics of cellular components of the target organ contribute to the character and possibly the intensity of the local immuno-inflammatory responses.

An autoimmune basis has been implicated in a number of cardiac diseases including rheumatic fever and myocarditis. In order to shed more light on the pathogenesis and etiology of this disease, additional studies are needed on identifying the basis of genetic predisposition to the disease, the role of cytokines, viral persistence, and the contribution of cardiac dendritic cells.

Both patients with diabetes mellitus and with systemic lupus erythematosus (SLE) are at higher risk of heart disease than the general population. Diabetes mellitus is a well-established major independent risk factor for coronary artery disease and peripheral vascular disease. In lupus, up to 50-60% of the patients have cardiac diseases such as endocarditis and pericarditis. A better understanding of the cardiac pathogenesis in these patients would lead to better treatment and possible prevention of cardiac disease progression. In addition, investigating the role of autoimmunity in atherosclerosis may shed new light on the etiology of syndromes such as systemic lupus erythematosus, an autoimmune disease in which death from coronary artery disease is increased. The mechanisms whereby heat shock proteins exacerbate lesion development, for example by binding to components derived from oxLDL thereby enhancing their antigenicity, is an under-investigated area that requires further study.

Idiopathic pulmonary fibrosis is associated with autoimmune diseases and can be the leading cause of death. Autoantibodies are found in association with idiopathic pulmonary fibrosis. The role for a unique tissue environment and factors have been cited as an important elements of the development of the autoimmune response. Given the exposure of the lung to viruses and the role for dysregulated inflammation in interstitial lung diseases, the possible role for an

autoimmune response in initiating or perpetuating the inflammation is potentially an important aspect of these diseases.

Scope

The purpose of this Request for Applications is to stimulate innovative and multidisciplinary studies of immune and non-immune mechanisms of induction and development of injury and dissection of the genetics of target organ involvement in the context of rheumatic and autoimmune diseases. Relevant diseases covered under this RFA include lupus, rheumatoid arthritis, scleroderma, Sjogren's disease, autoimmune skin diseases such as pemphigus and psoriasis, rheumatic fever and myocarditis, myositis and dermatomyositis, juvenile rheumatic diseases, autoimmune thyroid disease, insulin dependent diabetes mellitus, multiple sclerosis and other autoimmune diseases of the central and peripheral nervous system, celiac disease, inflammatory bowel disease, and autoimmune disease of the liver, autoimmune diseases involving the eye and the inner ear, and autoimmune kidney disease. New methodologies to facilitate studies of gene expression and characterization of the phenotype of involved tissues are needed. Knowledge gained by research in this area will make it possible to construct a more comprehensive picture of disease pathogenesis. Definition of discrete pathogenic processes involving the target organs may provide the scientific rationale for new forms of interventions.

Appropriate research areas may include, but are not limited to, the following:

o Development and evaluation of new experimental systems, including the generation of transgenic and other genetically-engineered animal models to study cellular, molecular, environmental, and genetic aspects of target organ involvement.

o Development of new in vitro models to analyze the effects of inflammatory, immune and other mechanisms of injury on target organ/cell function and structure.

o Identification and characterization of cellular and molecular pathways involved in target/end organ damage including damage caused by environmental agents.

o Mechanistic studies on the initiation and perpetuation of local immune and inflammatory responses that occur in organs involved in autoimmune diseases.

o Studies on the changes in target organ structure and function due to the presence of local immune, inflammatory and other forms of tissue injury related to the autoimmune disease.

o Studies on the effects of autoreactive or other relevant immune or inflammatory responses on target/end organ repair processes.

o Studies of mechanisms underlying phenotypic changes in cellular components of target organs during different phases of the disease.

o Identification of biochemical, structural or other markers that may correlate with early, preclinical target organ involvement and that may predict disease progression or severity.

o Analysis of environmental, genetic, and immune factors that determine the particular target organ involved.

o Studies to identify mediators and mechanisms that may either protect or exacerbate target organs from the inflammatory, immune and other forms of tissue injury involved in autoimmune diseases.

o Atherogenic determinants in autoimmune diseases such as lupus and anti-phospholipid antibody syndromes. Such studies could include neoepitope formation occurring as a result of oxidative modification of lipoproteins, phospholipids, or fatty acids, as well as studies to establish the significance of autoantibodies to lipoprotein oxidation products.

o The role of heat shock proteins in atherogenesis, the nature of hsp interactions with products of lipid metabolism and how and whether they contribute to the immunogenicity of such products and the regulation of hsp gene expression in vascular cells.

This list is intended to be illustrative and not exclusive or restrictive. Applications combining interdisciplinary approaches that include collaborations between autoimmune disease researchers and experts in other related scientific fields such as nephrology, neurology, etc. are strongly encouraged.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. If women or minorities are excluded or inadequately represented a clear compelling rationale must be provided. All investigators proposing research

involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994. This information is available on the internet at http://grants.nih.gov/grants/guide/notice-files/not94-100.html.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

LETTER OF INTENT

Prospective applicants are asked to submit, by April 9, 1999, a letter of intent that includes a title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows program staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-4952

FAX: (301) 480-4543
Email: broadwater@nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, e mail: GRANTSINFO@NIH.GOV.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

This solicitation uses Modular Grant Application and Award. In modular grant applications, total direct costs not exceeding $250,000 per year will be requested in $25,000 increments instead of being compiled from detailed and separate budget categories. The implementation of modular application, review and award procedures is described in http://grants.nih.gov/grants/guide/notice-files/not98-178.html

In preparing Modular Grant Applications, standard instructions for specific award mechanisms should be followed: [PHS 398 (R01,R21)] with these specific modifications reflecting modular budget and just-in-time concepts:

PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Use a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.)

At the top of the page, enter the total direct costs requested for each year.

o Under Personnel, list key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/ contractual arrangement is included in the overall requested modular direct cost amount.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm

- Complete the educational block at the top of the form page; - List current position(s) and then previous positions;
- List selected peer-reviewed publications, with full citations; - Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.

o CHECKLIST - This page should be completed and submitted with the application.

If the F&A rate agreement has been established, indicate the type of agreement and the date. It is important to identify all exclusions that were used in the calculation of the F&A costs for the initial budget period and all future budget years.

Additional information, including sample budget narratives and biographical sketch, may be found at this site: http://grants.nih.gov/grants/funding/modular/modular.htm.

Submit a signed original of the application, including the Checklist, and three signed copies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC-7710
BETHESDA, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must also be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-4952
FAX: (301) 480-4543
Email: broadwater@nih.gov

Applications must be received by May 12, 1999. If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the Institute staff. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NIAMS staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, a process will be used by the initial review group in which applications receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or method?

Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH Policy, all applications will also be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration in relation to the proposed research

o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

AWARD CRITERIA

The anticipated date of award is September 30, 1999.

Awards will be based upon the following criteria:

o scientific merit
o availability of funds
o programmatic priorities of the funding IC
o responsiveness to the RFA

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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Vivian Pinn, Ph.D.
Associate Director for Research
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FAX: (301) 402-1798
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Direct inquiries regarding fiscal matters to:

Ms. Carol Fitzpatrick
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-43B, MSC 6500
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Schedule

Letter of Intent Receipt Date: April 9, 1999
Application Receipt Date: May 12, 1999
Initial Review: July 1999
Second Level Review: September 1999
Anticipated Award Date: September 30, 1999

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, 93.847, 93.113 - Biological Responses to Environmental Health Hazards, and No. 93.856 - Microbiological and Infectious Disease Research, and No. 93.855 - Immunology, Allergy, and Transplantation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, public law 103-227, the pro-children act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the America people.

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